**Participant Information Sheet and Consent Form**

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| --- | --- |
| **Short Title** | **The STEPCARE Trial** |
| **Full Title** | Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation |
| **Protocol Number** | TGI-78372273 |
| **Project Sponsor** | The George Institute for Global Health, Sydney, Australia |
| **Principal Investigator** | ***[Insert local Principal Investigator]*** |
| **Location** | ***[Insert local site name]*** |

**We invite you to continue to take part in a research project**

**What is the project about?**

This project is about treatments that you have already received following your emergency presentation to hospital with a heart attack (cardiac arrest). The project compares commonly used strategies for sedatives, temperature and blood pressure.

**Why are we doing this project?**

An independent Ethics Committee have approved this project, which allows us to include you in the project during the period of emergency management; and then to ask for your permission to continue in the project afterwards. This is because of the emergency nature of your presentation to hospital, your impaired conscious level, and also because the strategies are all part of standard care in Australia and internationally. The project will allow us to improve the delivery of health care by comparing safe strategies already in use, to see if there is some advantage with one or the other.

**What does this project involve?**

You were assigned **either** to:

* A continuous **or** minimal sedation approach;
* Temperature control using a device in addition to medications **or** primarily using medications;
* a Higher **or** lower normal blood pressure strategy.

All trial interventions were started as soon as possible after your hospital presentation.

You received all usual medical and nursing care from the ICU team.

For the purposes of this project, de-identified information is collected from your medical record.

***Following discharge from hospital***

This aspect of the study is additional to usual hospital care that you receive. A project staff member from The George Institute will contact you (or a nominated person) on three occasions; at 30-days, 6 and 12-months to see how you are recovering and to ask some questions about your brain function, daily activities, mental wellbeing, and quality of life. The phone call at 30-days should take about 5 minutes. The 6 and 12-month follow-up visit/call involve questionnaires/interviews which last about an hour and will require some input from your primary relative/friend or carer.

**What are the risks?**

This project does not pose any extra risk to you as each of the strategies are part of usual clinical care. The known minimal risks are explained further in this form.

**What next?**

It is important that you read the rest of this document and ask any questions about anything you don’t understand or want to know more about. If you want to continue to take part in this trial, there is a section at the end for your signature. There is also a section if you would like to withdraw from the project.

**1. Introduction**

We invite you *to* *continue* to take part in the STEPCARE trial. You required emergency hospital treatment because your heart stopped (cardiac arrest). Once your heart was restarted by emergency personnel, you remained unconscious. In this setting, emergency medical treatments need to begin as soon as possible and this is how you have come to be included in the STEPCARE trial. This process is ethically approved by an independent ethics committee and is in accordance with the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) which was developed to protect the interests of people participating in human research studies in Australia.

Please take the time to read the following information and ask any questions about anything you don’t understand or want to know more about. You may find it helpful to talk about the trial with friends, family or your doctor.

Taking part in this research is voluntary. If you don’t want to take part, you don’t have to. You will receive the best possible care whether or not you take part.

**2. What is the purpose of this research project?**

Treatment for patients who are unconscious after a cardiac arrest requires emergency hospitalisation and urgent management. Emergency medical monitoring and treatment is necessary and includes the use of strategies and the setting of targets to maintain the optimal function of vital organs like the heart and brain. However, the best strategies and targets for these treatments are unknown and clinicians use a range of strategies and targets depending on their interpretation of the available evidence and guidelines. The STEPCARE trial compares commonly used strategies for (1) sedatives, (2) body temperature and (3) blood pressure.

The purpose of this trial is to find out if continuous sedation, fever management with a cooling device and a higher blood pressure target is associated with improved clinical outcomes after a cardiac arrest, compared with minimal sedation (early awakening), fever management primarily with medications, and a lower normal blood pressure target.

**3. What does participation in this research project involve?**

This project is a “randomised” clinical trial and this means that you have been allocated by a process similar to the tossing of a coin to each treatment strategy – one strategy for sedation, one for temperature and one for blood pressure. Neither the doctor nor you can decide which treatment you received.

The period of trial participation is 12 months.

The treatment strategies you were randomised to were started as soon as possible and continued for up to 36 (sedation) or 72 hours (temperature and blood pressure). Apart from the specific trial strategies, you received all usual medical and nursing care.

De-identified information is recorded in the project database from your medical record, apart from information needed for follow up after discharge and for the linkage of health records.

Participation in the trial will include the following:

*In the intensive care unit (ICU)*

**Sedation:** You received one of two approaches to sedative use. You had either continuous sedation for the first 36 hours allowing a period of brain rest before assessment of brain function; or minimised sedation use allowing earlier assessment of brain function.

**Temperature:** You had your temperature measured accurately using a urinary catheter that is part of usual care. You received one of two approaches for temperature management; either the use of a cooling machine if your body temperature rose above 37.7C, or the use of mainly medications for control of temperature.

**Blood pressure:** You had your blood pressure monitored via a probe placed in a blood vessel as part of usual care. You received one of two approaches for blood pressure management; either a normal blood pressure target or a slightly increased blood pressure target. Usual care involves using medications and intravenous fluids continuously to increase or lower the blood pressure as determined by the clinician.

*Following discharge from ICU*

Your general hospital care was not affected in any way by participation in this project.

*Following discharge from hospital*

We would like to follow you up at 30 days, 6 and 12-months after you were included in the trial. At 30 days, this will be a short phone call if you are no longer in hospital and you will be asked to complete one questionnaire to see how you are recovering. The 6 and 12-month follow-up visits will occur via a hospital visit, or a telephone or digital meeting. This will involve an interview and 11 questionnaires, will last about an hour, and will require some input from your primary relative/friend or carer.

 One questionnaire will be required to be completed by your primary relative/friend or carer to provide information on your health. Your primary relative/friend or carer will also be asked to participate in the follow-up with specific questions focused on their health and wellbeing. This will involve 7 questionnaires and may last about 45 minutes. If there are any concerns about your health or wellbeing during one of these phone calls, the trial staff will discuss these with you and assist by contacting your GP.

The questionnaires evaluate the effects of certain aspects of brain function and how these affect a person’s life on a day-to-day basis, such as:

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| --- |
| **30-Days Follow-up** |
| **Function** | **Questionnaire** | **Participant** | **Carer** |
| Affect on daily life | Modified Rankin Score (mRS) | X |  |
|  |
| **6 and 12-Months Follow-up** |
| **Function** | **Questionnaire** | **Participant** | **Carer** |
| Thinking, concentration and memory | Montreal Cognitive Assessment (MoCA) | X |  |
| Symbol Digit Modalities Test (SDMT) | X |  |
| Mental wellbeing | Hospital Anxiety and Depression Scale (HADS) | X | X |
| Post traumatic stress disorder | Post-Traumatic Stress Disorder (PTSD) Checklist (PCL-5) | X | X |
| Physical function | Time Stands Tests (TST) | X |  |
| Hand Grip Strength | X |  |
| Affect on daily life | Modified Rankin Score (mRS) | X |  |
| EUROqOL health Questionnaire (EQ 5D 5L) | X | X |
| World Health Organization Disability Assessment Scale (WHODAS) 2.0 | X | X |
| Modified Fatigue Impact Scale (MFIS) | X | X |
| Visual Analogue Scale (VAS) | X | X |
| Detailed questionnaire about return to work and rehabilitation | X |  |
| Zarit Burden Interview (ZBI) |  | X |
| Informant Questionnaire on Cognitive Decline in the Elderly -Cardiac Arrest version (IQCODE-CA) |  | X |

*Linkage of healthcare records*

Healthcare record linkage will be conducted at 6 and 12-months after you were included in the trial to assess the health services you used during this period (health economic analysis). The ICU trial staff will send your personal details (name, address, date of birth and medical record number) to The George Institute for Global Health via a secure file transfer protocol (SFTP). These details will then be sent to state and national data linkage units who will link your personal information with state and national databases to assess the health services you used over the specified period. The type of databases to be accessed will be hospital admission databases, registries of births deaths and marriages, and the Australian bureau of statistics. Then, your identifying information (name, address, date of birth and medical record number) will be removed and the information will be forwarded to the research team at The George Institute for Global Health for analysis. This data will be stored on a secure, password protected shared drive (supported by The George Institute for Global Health’s Information Technology Department), separately to the main data of the trial. In addition, we will collaborate with the international team at Helsingborg Hospital / Lund University, Sweden and the Copenhagen Trial Unit, Denmark to conduct an international health economic analysis. The anonymised Australian data that is collected and entered into the study database will be combined with the international data and analysed by the international study team. All anonymised linked data will be stored for 15 years following publication of the trial results and then confidentially destroyed, as required by law.

**4. What are the possible benefits of taking part in this research project?**

While we hope that this research furthers medical knowledge we cannot guarantee or promise that you will receive any direct health benefits from participating in this research.

The follow-up appointments consider the longer-term effects after having a cardiac arrest. They evaluate the effects of physical and mental function, and how these affect a person’s life on a day-to-day basis. These follow-up appointments would not be available outside of the trial and therefore this aspect of the trial may be beneficial to you as well as to your primary relative/friend or carer.

**5. What are the possible risks of taking part in this research project?**

Being included in the trial does not pose any extra risk to you, above the risks associated with the emergency and ongoing treatment that you need following your cardiac arrest. All strategies being evaluated in this trial are part of standard clinical care in Australia and internationally; as they are in common use, they have acceptable safety profiles and no one treatment is known to be better than another.

The known risks of sedative strategy include complications associated with a longer length of stay (infections and blood clots) with continuous sedation; and accidental removal of tubes and monitoring with minimal sedation.

The known risks of temperature strategy include shivering, infections, blood clots and bleeding with the use of devices; and liver and kidney abnormalities with medications.

The known risks of blood pressure strategy are a change in heart rhythm or heart strain with the higher blood pressure; and reduced blood flow with the lower normal blood pressure.

Your participation in this trial will be stopped if the treating clinical team feels it is not in your best interest to continue.

If you are concerned about any new or unusual symptoms, tell your doctor immediately.

**6. What if I withdraw from this research project?**

You can withdraw from the trial at any time without having to give a reason. If you choose to end your participation in the trial, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you. You will continue to receive the usual medical and nursing care. The trial doctor or one of the ICU staff members can talk to you about any medical issues if you choose to withdraw from the trial.

All information collected throughout the trial is helpful. If you choose to end your participation in the project, you can say whether you are happy for the research team to:

* Use all trial data (collected before and after date of withdrawal)
* Use trial data collected up to the date of withdrawal
* Access your medical record to obtain health information
* Contact you 30-days, 6 and 12-months after starting the trial to obtain health information
* Completion of follow-up questionnaires by you and your primary relative/friend or carer by telephone, digital meeting or face to face visit

While you are taking part in this trial, you will be kept informed of any significant new findings (if any) which may affect your willingness to continue in the trial.

If you choose to end your participation in the trial, please complete the ‘Participant Withdrawal of Consent Form at the end of this Information Sheet.

**7. Could this research project be stopped unexpectedly?**

This research project may be stopped for a variety of reasons, such as:

* + Unacceptable side effects
	+ The trial treatment being shown not to be effective
	+ The trial treatment being shown to work and does not need further testing; or
	+ Decisions made by local regulatory/health authorities

**8. How will your privacy be protected?**

By agreeing to take part in this trial your personal information (including your name, address, contact number) will be stored by staff at ***[insert name of local site]*** for the purpose of conducting this clinical trial. This personal information will remain securely stored in locked research offices at ***[insert name of local site].*** As required by law, this personal information will be kept for 15 years following publication of the trial results and then destroyed. This personal information constitutes a record of your participation in this trial.

In addition, you will be assigned a unique participant code as part of this clinical trial. Only the research team at ***[insert name of local site]*** can link your personal information to the participant code.

Information from your medical record, but no personal information, will be collected and stored with your participant code in a password protected database. This information (the unique participant code and the de-identified information from your medical record) will be entered into an electronic database that is managed securely by Spiral, New Zealand, with the main data server placed in Stockholm, Sweden (Spinnaker - Spiral Software (New Zealand: <https://spiral.co.nz/>)). This information is needed for scientifically evaluating the effects under investigation in this project – the Australian data needs to be collated with international data and the analysis will take place at The George institute for Global Health, Australia, Helsingborg Hospital/Lund UniversitySweden and Copenhagen Trial Unit, Copenhagen, Denmark.

Personal information may be disclosed to other research staff at ***[insert name of local site],*** collaborators and research partners, including staff at The George Institute for Global Health for the purposes of conducting this clinical trial. Personal information may need to be disclosed to regulatory bodies if required by law.

Your de-identified trial information may also be used for other research studies in the future; this will not include your personal details.

It is expected that the results of this trial will be published and presented at scientific meetings. In any publication or presentation, your personal information will not be used, only the analysis of the de-identified trial information that was in the study database. Results of the trial will be provided to you if you wish.

For further information about out how you may access and seek correction of your personal information and the steps you can take to make a complaint about the handling of your personal information, please see The George Institute for Global Health’s privacy policy (available at <https://www.georgeinstitute.org/privacy-policy>) or email: privacy@georgeinstitute.org.

**9. Who is organising and funding the research project?**

The trial is organised by Lund University (Sweden) and is the 4th study of an international collaboration that seeks to provide better treatments for patients who have had a cardiac arrest. Internationally it is planned that there will be 3500 participants from Europe, United Kingdom, Australia and New Zealand, with approximately 360 participants from Australia. The trial is funded by the Governments of Australia, Sweden and Finland at present – and has been designed by Investigators from Sweden (Helsingborg Hospital/Lund University), Finland and Australia.

The sponsor of this trial in Australia is The George Institute for Global Health. This project has received funding from The Medical Research Future Fund of Australia.

No money will be paid directly to individual researchers. There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

**10. Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**11. Compensation for injuries or complications**

If you suffer an injury or complication as a result of taking part in this trial, you should contact the trial doctor as soon as possible. They will help you to arrange appropriate medical treatment. Hospital care and treatment will be provided by the public health service at no extra cost to you if you are eligible for Medicare and choose to be treated as a public patient.

In addition, you may have a right to take legal action to obtain compensation for any injury or complication resulting from the trial. You do not give up any legal rights to compensation by taking part in this trial.

**12. Who can you contact?**

If you want any further information about this trial or if you have any medical problems which may be related to you taking part in the trial e.g. any side effects, please contact:

|  |  |
| --- | --- |
| Name | ***[Insert Name]*** |
| Position | ***[Insert Position]*** |
| Telephone | ***[Insert phone number]*** |
| Email | ***[Insert email address]*** |

For matters relating to research at the site at which you are taking part, the details of the local site complaints person are:

|  |  |
| --- | --- |
| Name | ***[Insert Name]*** |
| Position | ***[Insert Position]*** |
| Telephone | ***[Insert phone number]*** |
| Email | ***[Insert Email address]*** |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | Ethics Review Committee (RPAH Zone) of the Sydney Local Health District  |
| HREC Executive Officer | Executive Officer |
| Telephone | 02 9515 6766 |
| Email | SLHD-RPAEthics@health.nsw.gov.au |
| Protocol Number | X22-0393 |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

***Thank you for taking the time to consider this project. This information sheet is for you to keep.***

***If you wish to withdraw from the project, please sign the attached Participant Withdrawal of Consent Form.***

**Participant Consent Form**

*Adult providing own consent to continue*

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| --- | --- |
| **Short Title** | **STEPCARE Trial** |
| **Full Title** | Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation |
| **Protocol Number** | TGI-78372273 |
| **Project Sponsor** | The George Institute for Global Health, Sydney, Australia |
| **Principal Investigator** | ***[Insert local Principal Investigator]*** |
| **Location** | ***[Insert local site name]*** |

**Declaration by Participant**

* I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
* I have had the opportunity to ask questions and I am satisfied with the answers I have received.
* I understand the purposes, procedures and risks of the research described in the project.
* I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The George Institute for Global Health and research collaboratorsconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.
* I freely agree to take part in this research project as described and understand that I am free to withdraw at any time during the trial without affecting my future health care.
* I understand that my personal information will be handled in accordance with Australian privacy laws.
* I understand that I will be given a signed copy of this document to keep.
* I understand that, if I decide to discontinue the trial treatment, I may be asked to attend follow-up to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.
* I agree to my de-identified data being used for other research studies in the future. **□** Yes **□** No
* I would like a summary of the trial results when they become available. **□** Yes **□** No

My email address is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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|  |
|  | Name of Participant (please print): |  |  |  |  |
|  |
|  | Signature: |  |  Date: |  |
| **Declaration by Study Doctor/Senior Researcher†**I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation. |

**Declaration by trial Doctor/Senior Researcher**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  |
|  | Name of trial Doctor/Senior Researcher† (please print): |  |  |
|  |  |
|  | Signature: |  |  Date: |  |  |
|  |

Note: All parties signing the consent section must date their own signature.

**Participant Withdrawal of Participation Form**

|  |  |
| --- | --- |
| **Short Title** | **STEPCARE Trial** |
| **Full Title** | Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation |
| **Protocol Number** | TGI-78372273 |
| **Project Sponsor** | The George Institute for Global Health, Sydney, Australia |
| **Principal Investigator** | ***[Insert local Principal Investigator]*** |
| **Location** | ***[Insert local site name]*** |

**Declaration by Participant**

I wish to withdraw from participation in the above research trial and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Insert Institution].*

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

|  |  |
| --- | --- |
| Consent provided to use all trial data (collected before and after date of withdrawal) | Yes [ ]  No [ ]  |
| Consent provided to use trial data collected up to the date of withdrawal | Yes [ ]  No [ ]  |
| Consent provided to access medical record to obtain health information | Yes [ ]  No [ ]  |
| Consent provided to have data linkage to conduct health economic analysis | Yes [ ]  No [ ]  |
| Consent provided to contact the me at 30-days, 6 and 12-months after starting the trial to obtain health information | Yes [ ]  No [ ]  |
| Consent provided to complete the follow-up questionnaires by telephone or face to face visit to obtain health information | Yes [ ]  No [ ]  |

**Declaration by trial Doctor/Senior Researcher**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | Name of trial Doctor/Senior Researcher (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

In the event the participant decided to withdraw verbally, trial doctor/senior researcher to give a description of the circumstances below:

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|  |